Dietary supplements

NSF International Standard/ American National Standard

NSF/ANSI 173 – 2005

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NSF International Standard/
American National Standard
for Dietary Supplements —

Dietary supplements

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Foreword[2]

The purpose of NSF/ANSI 173 is to serve as an evaluation tool for analyzing dietary supplements. Certification to this Standard serves as a communication tool between manufacturers of ingredients and finished product, retailers, healthcare practitioners, and consumers. This Standard provides test methods and evaluation criteria to allow for the determination that a dietary supplement contains the ingredients claimed on the label, either qualitatively or quantitatively, and that it does not contain specific undeclared contaminants. In some instances, validated laboratory methods are not yet available for analyzing certain ingredients. In such cases, new methods will be added to this Standard as they become available.

NSF/ANSI 173 was developed with participation from the dietary supplements industry, public health regulators, and distributors of dietary supplements. Participation and technical guidance was provided by representatives of the American Herbal Products Association, the American Pharmaceutical Association, the Consumer Healthcare Products Association, the Council for Responsible Nutrition, the National Institutes of Health, and the National Nutritional Foods Association.

Section 8 contains requirements for Good Manufacturing Practices (GMPs) based on the GMPs submitted by industry to the U.S. Food and Drug Administration (USFDA) in November 1995.[3] When the USFDA publishes Good Manufacturing Practices, this document will be revised to be consistent with the USFDA's GMPs. Further clarification on the interpretation of these GMPs for certification to this Standard may be found in NSF's Certification Policies for Dietary Supplements.

This edition of the Standard (NSF/ANSI 173 – 2005) includes the following revisions:

– Section 2, Normative references, includes editorial changes and updates to current referenced documents as well as additional references.

– Additional language and requirements have been incorporated into section 5, Raw Materials, to include product requirements and evaluation associated with the types of common claims.

– An identification and quantitative quality assurance section has been added to section 6.

– A modification and additional language has been incorporated into sections 6 and 7 to support compliance with method validation requirements within the context of analysis for dietary supplements.

– A modification to the language in section 7.1, Test methods for metals, to more accurately reflect the evaluation(s) performed to measure contaminant levels of chromium (VI).

– Incorporate pentachlorophenol into the table in 7.2.2.

– Section 9, Records retention, has been reformatted to be included as a Good Manufacturing Practice and clarification of necessary label storage.

– Additional language has been added to sections 5 and 7 to set limits for peroxide used in dietary supplements oils.

[2] The information contained in this Foreword is not part of this American National Standard (ANS) and has not been processed in accordance with ANSI's requirements for an ANS. As such, this Foreword may contain material that has not been subjected to public review or a consensus process. In addition, it does not contain requirements necessary for conformance to the Standard.

[3] Federal Register, February 6, 1997 (Volume 62, Number 25), Docket No. 96 N-0417, 5699-5709

NSF offers a certification program to this Standard. Products certified by NSF carry the NSF Mark, the leading mark in public health and safety certification around the world. The NSF Mark on a product gives consumers and retailers assurance that the product meets the requirements of the NSF Standard. For more information on the NSF certification program, please contact Kathy Pompliano at NSF International, P.O. Box 130140, Ann Arbor, Michigan 48113–0140 or at 1-734-769-8010.

Suggestions for improvement of this Standard are welcome. Comments should be sent to Chair, Dietary Supplements, c/o NSF International, Standards Department, P.O. Box 130140, Ann Arbor, Michigan, 48113-0140, USA.

NSF International Standard
for Dietary Supplements —

Dietary supplements

1 General

1.1 Purpose

This Standard provides test methods and evaluation criteria for dietary supplement products to allow for the determination that the ingredients in the product are accurately identified and that the product contains the quantity of dietary ingredients and marker constituents declared on the product label and that the product does not contain unacceptable quantities of contaminants.

This Standard also provides criteria for determining that Good Manufacturing Practices were adhered to in the production of dietary supplements.

1.2 Scope

This Standard contains requirements for dietary supplements that bear or contain one or more of the following dietary ingredients: a vitamin, a mineral, a herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combinations of these ingredients. This Standard does not include products represented for use as conventional foods.

Products and ingredients deemed a hazard to public health or safety by a regulatory agency having jurisdiction shall be excluded from the scope of this document. Conventional foods shall be excluded from the requirements of this Standard.

2 Normative references

The following documents contain provisions that, through reference in this text, constitute provisions of this Standard. At the time this Standard was written, the edition indicated was valid. All documents are subject to revision, and parties are encouraged to investigate the possibility of applying the most recent edition of the document indicated below.

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Ashwagandha Root*, April 2000[4]

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Astragalus Root*, August 1999[4]

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Bilberry fruit*, 2001[4]

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Black Cohash root*, 2002[4]

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Black Haw Bark*, June 2000[4]

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Chaste Tree Fruit*, 2001[4]

[4] American Herbal Pharmacopoeia, PO Box 66809, Scotts Valley, CA 95067

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Cramp Bark*, February 2000[4]

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Cranberry*, 2002[4]

AHP, American Herbal; Pharmacopoeia and Therapeutic Compendium, *Dang Gui Root*, 2003[4]

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Ginkgo Leaf*, 2003[4]

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Goldenseal*, 2001[4]

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Hawthorn Berry*, June 1999[4]

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Hawthorn Leaf with Flower*, February 1999[4]

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Reishi Mushroom*, September 2000[4]

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *St. John's Wort*, July 1997[4]

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Schisandra Berry*, October 1999[4]

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Valerian Root*, April 1999[4]

AHP, American Herbal Pharmacopoeia and Therapeutic Compendium, *Willow Bark*, December 1999[4]

AHPA, American Herbal Products Association, *Herbs of Commerce*, 2nd Edition, 2000[5]

AOAC International, Food and Drug Administration, *Bacteriological Analytical Manual*, eighth edition (1998)[6]

AOAC International, *Official Methods of Analysis*, 17th ed.[6]

AOCS, American Oil Chemists Society International, *Sampling and Analysis of Commerical Fats and Oils*, Cd 18-90 (1997)[7]

BHP, British Herbal Medicine Association, *British Herbal Pharmacopoeia*, 1996[8]

Code of Federal Regulations, Title 40, (40 CFR) Part 141, *National Primary Drinking Water Regulations*[9]

Dietary Supplements Health and Education Act of 1994, (an amendment to the Federal Food, Drug and Cosmetic Act): Public Law 103-417 – October 25, 1994[10]

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[5] American Herbal Products Association, 8484 Georgia Ave., Suite 370, Silver Spring, MD 20910

[6] AOAC International, 481 Frederick Avenue, Suite 500, Gaithersburg, MD 20877

[7] AOCS, 2211 W. Bradley Ave., Champaign, IL 61821

[8] British Herbal Medicine Association, P.O. Box 304, Bournemouth, Dorset, BH7 6JZ, England

[9] U.S. Government Printing Office, Washington, DC 20402

[10] Superintendent of Documents, U.S. Government Printing Office, Washington, DC

INA, *Allicin by High-Performance Liquid Chromatography*[11]

INA, *Black Cohosh Assay by ELSD*[11]

INA, *Catechins and Gallic Acid in Green Tea by HPLC*[11]

INA, *Fatty Acid Content in Saw Palmetto by Gas Chromatography*[11]

INA, *Ginkgo Flavonol Glycoside Assay by HPLC*[11]

INA, *Ginkgoterpenoid Assay by HPLC*[11]

INA, *Kavalactone Assay by HPLC*[11]

INA, *Phenolics in Echinacea by HPLC*[11]

INA, *St. John's Wort Assay by HPLC*[11]

INA, *Sterols Content in Saw Palmetto by Gas Chromatography*[11]

International Code for Botanical Nomenclature (St. Louis Code), 2000[12]

NTIS/IEC 17025: 1999 *General requirements for the competence of testing and calibration laboratories*[13]

The Merck Index: *An Encyclopedia of Chemicals, Drugs and Biologicals* (Annual) [14]

NSF International White Book of NSF Registered and USDA Authorized Proprietary Substances and Nonfood Compounds[15]

Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 42 USC 201[9]

USEPA *Methods for the Determination of Metals in Environmental Samples – Supplement*, 1 – EPA/600/R-94-111 – May 1994[16]

USEPA *Microwave Assisted Acid Digestion of Sediments, Sludges, Soils and Oils*, EPA Method 3510- September 1994[16]

USEPA *National Primary Drinking Water Regulations* (40 CFR part 141) [16]

USFDA, *Bacteriological Analytical Manual,* eighth edition, 2001[16]

[11] Institute for Nutraceutical Advancement (INA), c/o NSF International, 789 Dixboro Road, Ann Arbor, MI 48105

[12] Sixteenth International Botanical Congress, St. Louis, Missouri, July-August 1999. Publ. 2000, Koeltz Scientific Books.

[13] National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161

[14] Merck & Company, Whitehouse Station, NJ

[15] NSF International, 789 North Dixboro Road, Ann Arbor, MI 48105

[16] USEPA, Office of Water, Washington, DC 20460

USFDA, *Pesticide Analytical Manual,* Volume 1. Multiresidue Methods [Base Manual 3rd Edition] 1994 – NTIS report number PB9294911899[17]

USFDA, *Pesticide Analytical Manual,* Volume 1 Updates. Irregular reports. 2003 – NTIS report number PB2003911800[17]

USFDA, *Pesticide Analytical Manual,* Volume 2. Methods for Individual Residues [Base Manual] – 1991 NTIS report number PB92911999[17]

USFDA, *Food Code 2001 Recommendations of the United States Public Health Service Food and Drug Administration,* NTIS report number PB2002100819[17]

USFDA, *Determination of Aristolochic Acid in Traditional Chinese Medicines and Dietary Supplements*[18]

USP, United States Pharmacopeia, USP 28-NF 23,[19]

WHO, *World Health Organization Monographs on Selected Medicinal Plants*, Volume 1[20]

WHO, *Guidelines for Drinking-Water Quality*[20]

3 Definitions

Terms used in this Standard that have special technical meaning are defined here.

3.1 active ingredient: Principal ingredient identified in product name or on the principal display panel.

3.2 adulteration: As defined by the Federal Food and Cosmetic Act, §402, adulterated food is defined in Title 21, USC §342.

3.3 batch or lot: A specific quantity of a finished product or other material that is intended to have uniform character and quality, within specified limits, and/or is produced according to a single manufacturing order during the same cycle of manufacture.

3.4 botanical ingredient: An ingredient of plant species or form.

3.5 chewable: A supplement intended to be reduced through mastication.

3.6 Class I: added nutrients.

3.7 Class II: naturally occurring (indigenous) nutrients.

3.8 dietary ingredient: An ingredient intended for use or used in a dietary supplement that is a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, or extract.

3.9 dietary supplement[14]**:** A product (other than tobacco) that:

[17] U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-0001

[18] USFDA Forensic Chemistry Center, Cincinnati, OH

[19] United States Pharmocopeia, 121601 Twinbrook Parkway, Rockville, MD 20852-1790

[20] World Health Organization, 1211 Geneva 27, Switzerland

– is intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, a herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combinations of these ingredients;

– is intended for ingestion in pill, capsule, tablet, powder, or liquid form;

– is not represented for use as a conventional food or as the sole item of a meal or diet;

– is labeled as a "dietary supplement;"

– includes an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351, of the Public Health Service Act (42 U.S.C. 262), and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice, and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 402(f), and does not include an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262) or an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful.

3.10 finished product: A product requiring no further processing prior to sale to the consumer.

3.11 Good Manufacturing Practices (GMP): A system of procedures and documentation, written or analytical, to assure the product produced has the identity, strength, composition, quality, and purity that it purports or is represented to possess.

3.12 in-process material: Any material fabricated, compounded, blended, ground, extracted, sifted, sterilized, derived by chemical reaction, or processed in any other way that is produced for, and used in, the preparation of a dietary ingredient or supplement prior to packaging as ready for sale.

3.13 lot number: Any distinctive combination of letters, numbers, or symbols, or any combination of them from which the complete history of the manufacture, processing, packaging, holding, and distribution of a batch or lot of a finished dietary ingredient, dietary supplement, or other material can be determined.

3.14 manufacture or manufacturing: All operations associated with the production of dietary supplements, including packaging, labeling, testing, and quality control of a dietary ingredient or dietary supplement.

3.15 marker constituent: A compound present in a botanical that is characteristic of the botanical and that is used for technical purposes and allows for the quantification of the ingredients incorporated into the product, e.g., identification of the botanical or process control.

3.16 measure of uncertainty: An estimation of the variability in an analytical result that can be reasonably expected based on the methodology employed. The estimate is based in part on parameters such as reproducibility, reference materials, and sample effects including matrix spike recoveries and scientific experience.

3.17 plant: Building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of a dietary product.

3.18 pest: Any objectionable animal or insect including, but not limited to, birds, rodents, insects, and larvae.

3.19 quality control system: A planned systematic procedure for taking all actions necessary to produce consistent, unadulterated dietary ingredients or dietary supplements.

3.20 quality control unit: Any person or organizational element designated by the firm to be responsible for the duties relating to quality control operations.

3.21 raw material: Any ingredient intended for use in the manufacture of a dietary ingredient or dietary supplement, including those that may not appear in such finished product.

3.22 representative sample: A sample that consists of a number of units that are drawn based upon rational criteria, such as random sampling, and is intended to assure that the sample accurately portrays the material being sampled.

3.23 rework: Clean, unadulterated material that has been removed from processing for reasons other than unsanitary conditions, or that has been successfully reconditioned by reprocessing, and that is suitable for use in the manufacture of a dietary product.

3.24 specifications: The quality parameters to which the products or materials shall conform and which serve as a basis for quality evaluation.

4 Labeling and literature requirements

Product labels shall declare the identity of dietary ingredient(s) and/or marker constituent(s) included in the product. Labels of products other than proprietary blends shall declare the quantity of each dietary ingredient(s) and/or marker constituent(s), which shall be labeled by common name according to Merck Index or in accordance with the appropriate regulatory agency guidance when available. Products containing botanicals shall include the part of plant from which the ingredients are derived. Common names of botanicals shall be in accordance with Herbs of Commerce or the International Code of Botanical Nomenclature. The amount of active or desired ingredient shall be listed in addition to the total amount of the ingredient. Product literature may also include this information. Labels shall comply with appropriate regulatory requirements.

5 Product requirements – verified by testing laboratories

All dietary supplements shall meet all applicable regulatory requirements.

5.1 Identity

5.1.1 Raw materials

The identity of the raw material shall be verified in accordance with 6.1 and/or 8 using those test method(s) appropriate for establishing identity based on the manufacturer's claims.

5.1.2 Finished product

All finished products shall contain each of the dietary ingredients and/or marker constituents declared on the label when tested in accordance with 6.1. The source of the ingredient shall be verified as listed on the label.

5.2 Quantity

5.2.1 Raw materials

The quantity of marker constituents shall be verified in accordance with 6.2 when declared on the certificate of analysis. Other declarations made in the Certificate of Analysis and/or the Raw Material Specification shall be verified in accordance with 6.2, 7.4 and/or 8.

5.2.2 Finished products

The quantity of dietary ingredients and/or marker constituents declared on the label shall be verified in accordance with 6.2 and/or 8. Nutritional declarations will be verified in accordance with 6.2 only when the quantity claimed is greater than 2% of the daily recommended value (DRV) (based on the reference caloric intake of 2,000 calories) as detailed in the following table (Ref. is 21 CFR 101.9).

Component	DRV (units)	Level requiring testing
cholesterol	300 g	> 6 g/serving
fat	65 g	> 1.3 g/serving
fiber	25 g	> 0.5 g/serving
potassium	3,500 mg	> 70 mg/serving
protein	50 g	> 1 g/serving
saturated fatty acids	20 g	> 0.4 g/serving
sodium	2,400 mg	> 48 mg/serving
total carbohydrate sugar	300 g	> 6 g/serving

The product shall contain at least 100% (minus the measure of uncertainty) of the quantity of each Class I dietary ingredient and/or marker constituent declared on the label.

The product shall contain at least 80% (minus the measure of uncertainty) of the quantity of each Class II dietary ingredient and/or marker constituent declared on the label. The product shall not contain quantities in excess of those permitted by GMP (manufacturer's specifications).

5.3 Contaminants

5.3.1 Metals

5.3.1.1 Raw materials

Raw materials shall not contain undeclared metals in amounts greater than the following:

- arsenic content shall not exceed 5 parts per million (ppm);
- cadmium content shall not exceed 0.3 ppm;
- chromium (VI) content shall not exceed 2 ppm;
- lead content shall not exceed 10 ppm; and
- mercury content shall not exceed 0.2 ppm.

5.3.1.2 Finished products

Finished products shall not contain undeclared metals at rates of intake greater than the following:

- arsenic content shall not exceed 0.01 milligrams per daily dose (mg/d);
- cadmium content shall not exceed 0.006 mg/d;
- chromium (VI) content shall not exceed 0.02 mg/d;
- lead content shall not exceed 0.02 mg/d; and
- mercury content shall not exceed 0.02 mg/d.

5.3.2 Pesticides

Unless manufacturers have controls in place to screen for pesticides or use certified organic ingredients as demonstrated in the GMP audit, a broad pesticide screen shall be performed to confirm compliance with USFDA and USEPA regulated limits and the absence of banned pesticides in botanical products.

Raw materials and finished products containing *Panax ginseng* or *Panax quinquefolius* shall not contain pesticides listed in section 7.2.2 (limit of detection < 10 ppb).

5.3.3 Microbiological contaminants

Raw materials shall not contain aflatoxins at levels > 20 ppb and shall not contain microorganisms in quantities greater than permitted in table 3.

Finished products shall not contain aflatoxins at levels > 20 ppb and shall not contain microorganisms in quantities greater than permitted in table 4.

Finished products in a liquid form with an alcohol content ≤ 50% shall not contain *Pseudomonas aeruginosa*.

Finished products with an alcohol content ≥ 50% are exempt from microbial testing.

5.3.4 Natural toxins

Botanicals listed in annex A shall not contain aristolochic acid (limit of detection = 0.5 μg/gm).

5.3.5 Known adulterants

Products shall be evaluated to ensure they do not contain known adulterants including, but not limited to, the following:

- *Eleutherococcus senticosus* shall not contain *Periploca sepium* root.
- *Plantago lanceolata* shall not contain *Digitalis lanata* leaf.
- *Scutellaria lateriflora* shall not contain *Teucrium chamaedrys*.
- *Stephania tetranda* shall not contain *Aristolochia fangchi*.

5.3.6 Other product claims

Claims that the product is free of a particular contaminant or substance shall be verified in accordance with 7.4 and/or 8.

5.4 Disintegration

Supplements shall be verified as meeting the requirements for disintegration when tested using the methods described in USP 25-NF 20. The minimum exposure time to immersion fluids shall not be less than 60 min. Chewables and liquid extracts are exempt from disintegration testing requirements.

5.5 Oils

Supplements containing oils at greater than 2% by weight of the formulation shall demonstrate non-rancidity of the ingredients by having a Peroxide Value (PV) of less than 10 milliequivalents/Kg oil, a p-Anisidine Value (p-AV) of less than 20 and a Total Oxydation (Totox) Number (p-AV + 2PV) of less than 26.

6 Test methods used by testing laboratories for identification and quantification of ingredients – raw materials and finished products

6.1 Identification test methods

6.1.1 Botanicals

6.1.1.1 Macroscopic test methods

The identity of products shall be evaluated by an appropriate qualified individual based on the information contained in the monographs listed in table 1.

6.1.1.2 Microscopic test methods

The identity of products shall be evaluated by an appropriate qualified individual based on the information contained in the monographs listed in table 1.

6.1.1.3 Chemical test methods

The identity of dietary ingredients shall be evaluated in accordance with the methods in table 1. If no method exists or if improved technology allows for a more accurate and precise method to be developed, one may be developed. The use of any new method shall require that a validation be performed, following the principles of the AOAC Single Lab Validation Guideline as a minimum, which includes an evaluation of specificity and reproducibility. More rigorous validation could follow according to the guidelines of ICH, FDA, GLP, CEN, AOAC, as appropriate.

6.1.2 Vitamins

The identity of vitamins shall be evaluated in accordance with the methods listed in the current year of USP and NF. If no method exists or if improved technology allows for a more accurate and precise method to be developed, one may be developed. The use of any new method shall require that a validation be performed, following the principles of the AOAC Single Lab Validation Guideline as a minimum, which includes an evaluation of specificity and reproducibility. More rigorous validation could follow according to the guidelines of ICH, FDA, GLP, CEN, AOAC, as appropriate.

6.1.3 Minerals

The identity of minerals shall be evaluated in accordance with the methods listed in the USP-NF. If no method exists or if improved technology allows for a more accurate and precise method to be developed, one may be developed. The use of any new method shall require that a validation be performed, following the principles of the AOAC Single Lab Validation Guideline as a minimum, which includes an evaluation of specificity and reproducibility. More rigorous validation could follow according to the guidelines of ICH, FDA, GLP, CEN, AOAC, as appropriate.

6.1.4 Other dietary supplement ingredients

An effort shall be made to seek out the most appropriate method to confirm claims for the product under evaluation. The source of these methods may include AOAC International, USP-NF, AHP, European, German, Japanese monographs, INA, etc. The use of any new method shall require that a validation be performed, following the principles of the AOAC Single Lab Validation Guideline as a minimum, which includes an evaluation of specificity and reproducibility. More rigorous validation could follow according to the guidelines of ICH, FDA, GLP, CEN, AOAC, as appropriate.

6.1.5 Quality assurance for identification test methods

Identification test methods shall be performed using certified reference standards or materials when available. These shall include vouchered specimens, certified reference materials, and/or single chemicals with established identity. To the extent to which it is feasible, the reference standard or material shall be prepared in the same manner as the sample being evaluated.

6.2 Quantification test methods

6.2.1 Botanicals

If declared on the label, the identity of marker constituents shall be evaluated in accordance with the methods in table 2. If no method exists or if improved technology allows for a more accurate and precise method to be developed, one may be developed. The use of any new method shall require that a validation be performed, following the principles of the AOAC Single Lab Validation Guideline as a minimum, which includes an evaluation of specificity, linearity, reproducibility, accuracy, spike recovery and method detection limit (if applicable). More rigorous validation could follow according to the guidelines of ICH, FDA, GLP, CEN, AOAC, as appropriate.

6.2.2 Vitamins

The quantity of vitamins shall be evaluated in accordance with the methods listed in the USP-NF. If no method exists or if improved technology allows for a more accurate and precise method to be developed, one may be developed. The use of any new method shall require that a validation be performed, following the principles of the AOAC Single Lab Validation Guideline as a minimum, which includes an evaluation of specificity, linearity, reproducibility, accuracy, spike recovery and method detection limit (if applicable). More rigorous validation could follow according to the guidelines of ICH, FDA, GLP, CEN, AOAC, as appropriate.

6.2.3 Minerals

The quantity of minerals shall be evaluated in accordance with the methods listed in the USP-NF. If no method exists or if improved technology allows for a more accurate and precise method to be developed, one may be developed. The use of any new method shall require that a validation be performed, following the principles of the AOAC Single Lab Validation Guideline as a minimum, which includes an evaluation of specificity, linearity, reproducibility, accuracy, spike recovery and method detection limit (if applicable). More rigorous validation could follow according to the guidelines of ICH, FDA, GLP, CEN, AOAC, as appropriate.

6.2.4 Other dietary supplement ingredients

An effort shall be made to seek out the most appropriate method to confirm claims for the product under evaluation. The source of these methods may include AOAC International, USP-NF, AHP, European, German, Japanese monographs, INA, etc. The use of any new method shall require that a validation be performed, following the principles of the AOAC Single Lab Validation Guideline as a minimum, which includes an evaluation of specificity, linearity, reproducibility, accuracy, spike recovery and method detection limit (if applicable). More rigorous validation could follow according to the guidelines of ICH, FDA, GLP, CEN, AOAC, as appropriate.

6.2.5 Quality assurance for quantitative test methods

6.2.5.1 Calibration

Quantification test methods shall be performed using certified reference standards as calibration standards. The standards are typically purchased as single chemicals with greater than 95% purity. If a high purity standard is not available, a lower purity material shall be used if there is a means by which the actual purity can be measured (i.e. uv absorbance, etc).

6.2.5.1.1 Multi-level calibration curves

Multi-level calibration curves shall be prepared with a minimum of 3 concentration levels such that any sample preparations under evaluation would be bracketed by a calibration standard. Curves shall give a correlation coefficient of 0.995 or higher.

6.2.5.1.2 Single-level calibration curves

If a single level calibration is employed, the standard shall be run in triplicate and the relative standard deviation between these runs shall not exceed 2%. The detector response of the prepared sample shall be within 90% -%110 of that of the standard.

6.2.5.1.3 Blanks

A method/reagent blank shall be included in each analytical run.

6.2.5.1.4 Reproducibility/accuracy

All unfamiliar matrices shall be prepared in triplicate.

Whenever possible, two additional preparations shall be spiked with the reference standard(s) to assess recovery/accuracy. The reproducibility between the two spiked samples as measured by percent relative difference shall be no greater than 20%.

NOTE – When spiking with the reference standard is price prohibitive, a control sample with a known result shall be tested as part of the analysis run; this shall include a certified reference material or a sample that has been analyzed in the past.

6.2.5.1.5 Continuing Calibration Verification (CCV)

Continuing Calibration Verification (CCV) standards shall be run after every 10 sample preparations and/or at the end of the run. The recovery for the CCV shall be within the uncertainty of the method for the data to be acceptable. CCV standards, which are run to confirm an existing calibration, must show recovery of 90-110%. If the result falls outside this range, a new calibration shall be run.

7 Test methods used by testing laboratories for detection of contaminants – raw materials and finished products

7.1 Test methods for metals

The presence of arsenic, cadmium, chromium (Total) (see following note), lead, and mercury (elemental) shall be measured in accordance with the following methods:

– sample preparation method: Samples shall be prepared by microwave assisted acid digestion using a closed cell unit equipped with temperature monitoring. The temperature program and the

selection of reagents shall be modified or optimized as appropriate for the product being evaluated; and

– analytical method: USEPA 200.7 *Metals: Inductively Coupled Plasma-Atomic Emission Spectrophotometric Method for Trace Element Analysis of Water and Wastes*. Alternate methodologies, such as graphite furnace atomic emission spectrophotometry, ICP-MS, and flow injection analysis may be used for specific samples at the discretion of the analyst.

NOTE – If the chromium (total) result exceeds the pass/fail criteria (5.3.1), levels of Cr (VI) will be determined using a liquid chromatography method based on EPA Method 218.6. Modifications to the sample preparation and extraction procedures will be employed based on the dietary supplement product or ingredient matrix.

7.2 Pesticides

7.2.1 Multi-residue method

The multi-residue method contained in the USFDA's Pesticide Analytical Manual I (PAM 1) shall be used to evaluate botanical products unless manufacturers have controls in place to screen for pesticides or use certified organic ingredients as demonstrated in the GMP audit.

7.2.2 Test methods for pesticides in *Panax ginseng* and *Panax quinquefolius*

Products containing *Panax ginseng* or *Panax quinquefolius* shall be evaluated based on the methods of the USFDA's Pesticide Analytical Manual I (PAM 1) for the presence of the following pesticides:

alpha-benzene hexachloride
beta-benzene hexachloride
delta-benzene hexachloride
hexachlorobenzene
lindane (gamma-benzene hexachloride)
pentachloroaniline
pentachlorobenzene
pentachlorophenol
pentachlorothioanisole
quintozene (pentachloronitrobenzene)
tetrachloroaniline

7.3 Test methods for microbiological contaminants

7.3.1 Aflatoxins

Testing shall be performed based on the methods described in Chapter 49, Natural Toxins, pp 49-1 to 49-49 of the AOAC *Official Methods of Analysis*.

7.3.2 Yeast and mold

Testing shall be performed based on the USP Plate Count Method under Total Aerobic Microbial Count substituting Potato Dextrose Agar and altering the incubation time/temperature to 5-7 d at 25 °C (77 °F).

7.3.3 Bacteria – total aerobic count

Testing shall be performed based on the USP Total Aerobic Microbial Count.

7.3.4 Enterobacteriaceae

Testing shall be performed based on the USP Total Aerobic Microbial Count substituting m-endo agar as the agar medium.

7.3.5 *Salmonella* sp

Testing shall be performed based on the USP Test for *Salmonella* sp.

7.3.6 *Escherichia coli*

Testing shall be performed based on the USP Test for *E. coli*.

7.3.7 *Staphylococcus aureus*

Testing shall be performed based on the USP Test for *S. aureus*.

7.3.8 *Pseudomonas aeruginosa*

Testing shall be performed based on the USP Test for *P. aeruginosa*.

7.4 Test methods for chemical contaminants

Testing shall be performed based on USFDA's Method for Determination of Aristolochic Acid in Traditional Chinese Medicines and Dietary Supplements.

The most appropriate method shall be used to confirm claims for the product under evaluation. The source of these methods may include AOAC International, USP, EPA, FDA, AHP, European, German, Japanese monographs, INA, industry standards, etc. The use of any new method shall require that a validation be performed which includes an evaluation of specificity, linearity, reproducibility, spike recovery and method detection limit. More rigorous validation could follow according to the guidelines of ICH, FDA, CEN, GLP, AOAC, as appropriate.

Unless manufacturers have controls in place to assess the rancidity of oil ingredients, the following testing shall be performed. The Peroxide Value of the oil shall be tested according to AOAC Method 965.33 (which is equivalent to AOCS 8-53). The p-Anisidine Value of the oil shall be tested by AOCS Cd 18-90.[7] he Totox Number will be calculated as the sum of the p-Anisidine Value and two times the Peroxide Value.

The most appropriate method shall be used to confirm claims for the product under evaluation. The source of these methods may include AOAC International, USP, EPA, FDA, AHP, European, German, Japanese pharmacopoeial monographs, INA, industry standards, etc. The use of any new method shall require that a validation be performed which includes an evaluation of specificity, linearity, reproducibility, spike recovery and method detection limit. More rigorous validation could follow according to the guidelines of ICH, FDA, CEN, GLP, AOAC, as appropriate.

8 Good Manufacturing Practices

Written procedures shall be established and followed for the maintenance of Good Manufacturing Practices.

8.1 Personnel

8.1.1 Disease control

Any person who has an illness or medical condition, such as, but not limited to, open lesions or infected wounds, that could be a possible source of microbial contamination shall be removed from the manufacturing process so as to prevent adulteration of the product during manufacture and storage. Personnel shall be instructed to report such health conditions to their supervisors.

Written procedures shall be established and followed for these procedures.

8.1.2 Cleanliness

All personnel having direct contact with raw materials, in-process materials, exposed products, and packaging components, as well as those individuals utilizing processing equipment and utensils, shall conform to a level of basic hygiene and personal cleanliness while on duty to protect the product against adulteration. These methods may include but are not limited to:

– wearing outer garments that protect against the adulteration of products and equipment;

– maintaining personal cleanliness;

– washing hands thoroughly before starting work and at any other time when the hands may have become soiled or contaminated;

– removing all unsecured jewelry and hand jewelry or covering hand jewelry that cannot be removed;

– using gloves that are maintained in an intact, clean, and sanitary condition;

– wearing hair nets, caps, beard covers, arm covers, or other effective hair restraints;

– storing clothing or other personal effects outside of processing areas;

– preventing personal care products from entering product; and

– excluding the consumption of food, drink, and medication, as well as the use of chewing gum and tobacco products in the processing areas.

Written procedures shall be established and followed.

8.1.3 Education and training

All personnel shall have written job descriptions and possess education, training, and/or experience to perform their assigned functions. All personnel shall receive GMP education and training to perform their assigned functions.

Written records of education and training shall be retained and routinely updated in order to document education and training progress.

Written procedures shall be established and followed.

8.1.4 Supervision

The responsibility for assuring compliance by all personnel with these requirements shall be assigned to qualified personnel with the proper education, training, and/or experience.

Written procedures shall be established and followed.

8.2 Plant and grounds

8.2.1 Grounds

The grounds of a manufacturing plant shall be kept in a condition that protects against adulteration of product. Methods shall include but are not limited to:

– storing equipment properly and removing litter, waste, and vegetation that could attract or harbor pests within the immediate vicinity of buildings;

– maintaining roads, yards, parking lots, and drainage areas to prevent product adulteration or harbor pests; and

– disposing of all waste and rubbish so as to prevent adulteration of the dietary product during manufacture and storage and to ensure a clean, safe work environment.

Written procedures shall be established and followed.

8.2.2 Plant construction and design

Plant buildings and structures shall be of a size, construction, and design to facilitate maintenance, cleaning, and sanitary operation and to prevent mix-ups between different raw materials and finished products. The plant facilities shall:

– provide sufficient space for placement of equipment and storage and segregation of materials;

– provide operating practices or effective design that reduces the potential for mix-ups or adulteration of in-process or finished products;

– facilitate maintenance functions including cleaning, sanitation, waste treatment and disposal, and elimination and prevention of pest infestations;

– provide adequate lighting in manufacturing areas;

– provide safety-type light bulbs, fixtures, and skylights to protect against possible adulteration by glass breakage;

– provide ventilation, air filtration, heating, and/or cooling to control microorganisms, dust, humidity, and temperature in order to prevent adulteration of product, and to provide a safe, clean work environment; and

– provide adequate screening or other protection against pests.

Written procedures shall be established and followed.

8.3 Sanitation of buildings and facilities

8.3.1 General maintenance

All buildings, structures, fixtures, and equipment shall be constructed in such a manner that floors, walls, ceilings, work surfaces, and equipment can be cleaned and sanitized. All buildings and fixtures shall be maintained in a sanitary condition and shall be kept in good repair.

Written procedures shall be established and followed.

8.3.2 Cleaning and sanitizing agents

Cleaning and sanitizing agents, pesticide chemicals, and fungicides shall be safe and effective for their intended use. NSF registered proprietary substances and non-food compounds are acceptable when used for their intended use.

Cleaning and sanitizing agents, pesticide chemicals, and fungicides shall be identified, used, held, and stored in a manner that protects against adulteration of raw materials, in-process or finished products, or contamination of processing equipment, utensils, or packaging materials.

Written procedures shall be established and followed.

8.3.3 Pest control

Effective means shall be taken to exclude pests from the entire plant. The use of insecticides or rodenticides is permitted only with precautions and restrictions that protect against adulteration of raw materials, products, equipment, or packaging materials.

No evidence of pests shall be present on product or packaging or in the area.

Pest control inspections shall be performed routinely.

Written procedures shall be established and followed.

8.3.4 Water supply

Potable water, as a minimum quality water, at designated temperature and pressure where appropriate, shall be provided in all areas where required for processing and cleaning or for employee sanitary facilities. Water shall meet or exceed the standards prescribed in the USEPA National Primary Drinking Water Regulations (40 CFR part 141) or the WHO Guidelines for Drinking-Water Quality.

Written procedures shall be established and followed for these procedures.

8.3.5 Plumbing

Plumbing shall be of a size and design and installed and maintained to:

- carry sufficient quantities of water to required locations throughout the plant;
- properly convey sewage and liquid waste from the plant;
- avoid adulteration of product or contamination of water supplies or equipment;
- provide floor drainage in areas where floors are subject to flooding; and
- prevent contamination of fresh water with discharge wastewater or sewage.

Written procedures shall be established and followed.

8.3.6 Sewage disposal

Sewage shall be disposed into a properly maintained and approved sewage system that complies with local regulatory requirements.

Written procedures shall be established and followed.

8.3.7 Toilet facilities

Each plant shall provide its employees with readily accessible toilet facilities. Each plant shall maintain toilet facilities in a sanitary condition, properly stocked, and in good repair at all times. Each plant should provide self-closing doors that do not open into areas where materials and/or product are exposed to airborne contamination.

Written procedures shall be established and followed.

8.3.8 Hand-washing facilities

Hand-washing facilities shall be convenient and furnished with tempered running water and shall include:

– hand-washing facilities at each location where employees are required to wash their hands;

– effective hand-cleaning and sanitizing preparations;

– air dryers or sanitary towel services;

– devices or fixtures that protect against the recontamination of clean, sanitized hands; and

– signs directing employees to wash hands before they start work, after each absence from their work station, or when their hands have become soiled or contaminated.

Written procedures shall be established and followed.

8.3.9 Rubbish disposal

Refuse receptacles and rubbish disposal practices that protect against adulteration or the harborage of pests shall be provided.

Written procedures shall be established and followed.

8.3.10 Supervision

The overall sanitation of the plant shall be under the supervision of one or more designated individuals with qualifications based on education, experience, and/or training.

Written procedures shall be established and followed.

8.4 Equipment and utensils

8.4.1 Design and construction

Equipment shall be constructed, installed, and maintained so as to facilitate the cleaning and disinfection of the equipment and the surrounding areas. Equipment shall be used for its intended purpose.

Equipment and utensils having direct contact with product shall be constructed of inert, non-toxic materials and designed to withstand the environment to which it is subjected during the manufacturing process and during cleaning and disinfection.

Seams on utensils and processing equipment shall be smoothly bonded or maintained to minimize the accumulation of residues and the opportunity for growth of microorganisms.

All plant equipment and utensils shall be designed, constructed, and maintained to preclude the adulteration of raw materials, packaging materials, in-process materials, and finished product with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

Cleaners, disinfectants, sanitizers, lubricants, and/or coolants used on utensils and processing equipment shall be suitable for use in food processing.

All equipment with critical parameters that require monitoring shall have suitable measuring devices such as time, temperature, pressure, and/or speed controls, etc.

Each freezer and cold storage compartment shall be fitted with a temperature-measuring device, automatic control, or alarm system.

Compressed air and other gases that come into contact with a product or ingredient or are used to clean equipment or utensils shall be treated in such a way that the materials with which they come in contact are not adulterated.

Instruments and controls shall be accurate and maintained.

Written procedures shall be established and followed.

8.4.2 Sanitation of equipment and utensils

All utensils and equipment shall be cleaned as frequently as necessary to ensure quality and integrity of the product using safe cleaning and sanitizing agents, then stored in a manner that protects against recontamination.

A written record of major equipment cleaning and use shall be maintained in individual equipment logs that show the date, product, and lot number of each batch processed and the cleaning or maintenance performed. The person(s) performing the cleaning and/or maintenance shall record in the log that the work was performed. Entries in the log shall be in chronological order. Manufacturers shall provide rationale for the selection of cleaning and sanitizing methods.

Written procedures shall be established and followed.

8.5 Quality assurance/control and laboratory operations

8.5.1 Quality assurance/control operations

Quality control operations shall be employed to assure products conform to standards of purity, quality, and composition and that packaging materials are safe for their intended purposes.

Written procedures shall be established and followed.

8.5.2 Quality assurance/control unit

There shall be a quality assurance/control unit that has the responsibility and final authority to:

– approve or reject all procedures, specifications, controls, test methods, and results that impact the purity, quality, and composition of an ingredient or product;

– approve or reject all raw materials, packaging materials, labeling, and finished products, including contract-manufactured products based upon conformance to established specifications;

– review that completed production records have the final authority to determine if the product is approved for distribution. This evaluation shall be documented and maintained as part of the batch record;

– establish procedures for changing or revising all documentation (such as procedures, methods, record keeping, formulas, etc.);

– review and approve all changes to documentation (such as procedures, methods, record keeping, formulas, etc.);

– assure that the most current revision of all documentation (such as procedures, methods, record keeping, formulas, etc.) is in use at all times;

– implement corrective action when documented procedures are not followed; and

– approve or reject deviations committed in the manufacturing of a product.

GMP internal audits shall be performed by the quality control unit periodically with documented corrective action kept on file.

The responsibilities and procedures applicable to the quality control unit shall be established in writing and followed.

Written procedures shall be established and followed.

8.5.3 In-house and/or contract laboratories

In-house and/or contract laboratories shall be available for performance of the quality assurance/control tasks and responsibilities.

Written procedures shall be established and followed.

8.5.4 Test methods

All test methods used for ingredient and product testing shall be reliable and yield appropriately reproducible and accurate results.

Written procedures shall be established and followed.

8.5.5 Laboratory records

Records of laboratory data derived from all specified tests shall be maintained.

Written procedures shall be established and followed.

8.5.6 Shelf life

All products shall bear an expiration date or a statement of product shelf life as appropriate or dictated by governing regulatory authorities. These dates shall be supported by data and/or rationale to reasonably assure the product meets manufacturer's established specifications throughout the product shelf life.

Accelerated stability studies or data from similar product formulations may be used for an initial determination of shelf life. Product shelf life may be confirmed and may be extended on the basis of real-time studies on product stored under labeled storage conditions.

Manufacturer's established specifications may include organoleptic or other qualitative or quantitative testing.

Written procedures shall be established and followed.

8.6 Production and process controls

8.6.1 Master production and control records

A master production and control record (e.g., manufacturing formula, raw materials specifications, component specifications, finished product specifications) shall be prepared for the manufacture of each product and shall be reviewed and approved by the quality control unit.

Master production and control records shall include:

– a complete list of raw materials used in the manufacture of the product, designated by names or codes sufficiently specific to indicate any special quality characteristic(s) and other specifications;

– the amount of each raw material used. Each batch shall be formulated to provide not less than 100% of each claimed dietary ingredient throughout the shelf life of the product;

– the name and weight or measure of each dietary ingredient per unit or portion or per unit of weight or measure of the product;

– a statement of the total weight or measure of any dietary supplement unit;

– a statement of the theoretical weight or measure of the manufactured product and the acceptable range beyond which an investigation is required;

– a description of the product container(s), closures(s), and product label(s), including positive identification of all labeling used; and

– manufacturing and process control instructions.

Written procedures shall be established and followed.

8.6.2 Batch production and control records

Batch production and control records shall be prepared and followed for each batch of product. These records shall include complete information relating to the production and control of each batch. These records shall be an accurate reproduction of the appropriate master production and control record and shall include documentation that each significant step in the manufacturing process was accomplished, including:

– dates;

– identity of individual major equipment and lines used;

– specific identification, including lot number, of each raw material or in-process material used;

– weight or measure of each raw material used in the course of processing;

– if performed, in-process testing results;

– quality control results;

– inspection of the packaging and labeling areas;

– a statement of the actual yield at the conclusion of each critical process step of the manufacture and a statement of the percentage of theoretical yield, as appropriate;

– label control records, including specimens, copies, or records of all labels used;

– description of product containers and closures used;

– any special notes of investigations or deviations from the described process; and

– identification of the persons performing and directly supervising described process.

Any deviations from written and approved specifications, standards, and test methods shall be recorded on the batch record and justified.

Written procedures shall be established and followed.

8.6.3 Handling and storage of raw materials, in-process materials, and rework

Raw materials, in-process materials, and rework shall be inspected and segregated or otherwise handled as necessary to verify they are clean and suitable for processing. They shall be stored and transported under conditions that protect against adulteration and minimize deterioration.

Containers of raw materials shall be inspected upon receipt to assure that their condition has not contributed to the adulteration or deterioration of the contents.

Raw agricultural materials that contain soil or other extraneous material shall be washed or cleaned, as necessary.

Raw materials, in-process materials, and rework shall be held in bulk or in containers and under conditions of temperature and humidity that prevents the materials from becoming adulterated or contaminated.

Written procedures shall be established and followed for the receipt, identification, examination, handling, sampling, testing, and approval or rejection of raw materials.

Written procedures shall be established and followed for the receiving, processing, storage, and final delivery of product requiring temperature control.

Each lot of raw material shall be identified with a distinctive lot number and shall be controlled according to its status (e.g., quarantined, approved, or rejected).

Each lot of raw material, in-process material, and rework that is liable to adulteration with filth, insect infestation, or other visually evident extraneous materials shall be examined against established specifications.

Each lot of raw material, in-process material, and rework that is liable to microbiological contamination that is objectionable in view of its intended use shall be subjected to microbiological tests before use.

Raw materials and other ingredients susceptible to adulteration with aflatoxin or other natural toxins shall comply with current USFDA regulations, guidelines, and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into a finished dietary ingredient or dietary supplement.

At a minimum, a representative sampling/testing program shall be in place to evaluate the presence of microbial contamination, aflatoxin or other natural toxins, and all other established specifications.

Written procedures shall be established and followed to verify the identity of each lot of raw material.

Approved raw materials shall be rotated so the oldest approved stock is used first.

Raw materials shall be retested or reexamined after a specified time in storage or after exposure to conditions that are likely to adversely affect the purity, quality, or composition of the raw material.

Rejected raw materials shall be identified and controlled under a system that prevents their use in manufacturing or processing operations, and they shall be stored in separate storage facilities.

Written procedures shall be established and followed.

8.6.4 Manufacturing operations

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of dietary products shall be conducted in accordance with sanitation principles in a manner that provides protection against adulteration from chemical, microbiological, or other extraneous sources.

Written procedures shall be established and followed for all inspection, manufacturing, packaging, and storage operations.

Effective measures shall be taken to segregate raw materials, packaging materials, in-process materials, rework, and finished products.

All containers, processing lines, and major equipment used during the production of a batch shall be identified at all times to indicate their contents.

Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in the product.

Effective measures shall be taken for the identification, storage, and disposal of rejected or adulterated products.

Written procedures shall be established and followed that describe tests to be conducted to assure the purity, compositions, and quality of the finished product.

Written procedures shall be established and followed prescribing the method for reprocessing batches that do not conform to finished goods standards or specifications.

Written procedures shall be established and followed.

8.6.5 Packaging and labeling operations

Filling, assembling, packaging, and other operations shall be performed in such a way that products are protected against adulteration.

Written procedures shall be established and followed for the receipt, storage, and examination of packaging materials.

Labels for each different product type, strength, or quantity of contents shall be stored separately and controlled in a manner consistent with Good Manufacturing Practices.

Obsolete labels, labeling, and other packaging materials shall be destroyed and such destruction documented in writing.

Written procedures shall be established and followed to assure that the correct labels, labeling, and packaging materials are issued and used.

Packages shall be identified with a lot number that permits determination of the history of the manufacture and control of the batch.

Packaging shall be examined to provide assurance that the containers and packages in the lot have the correct labels and lot numbers.

Written procedures shall be established and followed.

8.7 Warehousing, distribution, and post-distribution processes

8.7.1 Storage and distribution

Storage and transportation of finished product shall be conducted under conditions that protect product against physical, chemical, and microbial adulteration, as well as deterioration of the product and container.

Distribution records shall be maintained and retained for at least one year beyond the expiration date or shelf life.

Written procedures shall be established and followed.

8.7.2 Written recall procedures

Procedures shall be established and followed that define the recall of product(s) should it become necessary.

Written procedures shall be established and followed.

8.7.3 Complaint files

Written procedures shall be established and followed for the handling of all written and oral product complaints. Such procedures shall provide for review by the quality control unit and the determination of the need for an investigation.

A written record of each complaint shall be maintained for at least one year after the expiration or shelf life date of the product, or one year after the date that the complaint was received, whichever is longer. The written record shall include, where known, the name and description of the product, lot number, source and nature of the complaint, and response, if any. When an investigation is conducted, the written record shall include the findings of the investigation and follow-up action taken.

8.7.4 Returned products

Returned products shall be identified as such and held. Unless examination, testing, or other investigations prove the product meets standards of purity, composition, and quality, it shall be controlled to prevent redistribution.

A returned product may be reprocessed provided that the subsequent product meets appropriate quality and safety specifications.

Records pertaining to returned products that are reprocessed and/or redistributed shall be maintained and shall include the name and description of the product, lot number, reason for the return, quantity returned, date of disposition, and ultimate disposition of the returned product.

Records shall be maintained for at least one year after the expiration or shelf life date of the batch of product.

Written procedures shall be established and followed.

8.7.5 Product salvaging

Products that have been subjected to improper storage conditions including, but not limited to, hazardous chemicals, extremes in temperature, humidity, smoke, fumes, pressure, age, or radiation due to natural disasters, fires, accidents, or equipment failures shall not be salvaged and returned to the marketplace.

Written procedures shall be established and followed.

8.7.6 Defect action level

Some dietary ingredients and dietary supplements, even when produced under GMP, contain natural or unavoidable defects that at low levels are not hazardous to health. The USFDA and other applicable regulatory agencies have established maximum levels for these defects in foods produced under GMP and uses these levels in deciding whether to recommend regulatory action.

Defect action levels shall also be established for dietary products whenever it is necessary and feasible to do so. The manufacturer of a dietary product shall utilize quality control operations that reduce natural or unavoidable defects to the lowest level that is currently feasible.

The mixing of a dietary ingredient or dietary supplement containing defects beyond any established defect action level with another lot of dietary ingredient or dietary supplement shall not be permitted and renders the final lot adulterated, regardless of the defect level of the final product.

Written procedures shall be established and followed.

8.7.7 Reserve samples

A reserve sample of each raw material and each batch of a product, at least twice the quantity necessary to perform all the required tests, shall be retained, packaged, and stored under conditions consistent with the product labeling until at least one year after the expiration date.

Written procedures shall be established and followed.

8.8 Files for substantiation of health claims and statements of nutritional support

A file shall be maintained that includes information for substantiating health claims and statements of nutritional support.

Written procedures shall be established and followed.

8.9 Compliance with *The Public Health Security and Bioterrorism Preparedness and Response Act of 2002.*

Manufacturers of Dietary Supplements shall submit application to US FDA for registration, receive a Registration Number, and shall provide the Registration Number upon request.

8.10 Records retention

Written procedures shall be established and followed for record keeping.

Regulatory inspections shall be kept on file with documented corrective action.

Any testing, production, control, or distribution record and records required for Good Manufacturing Practices shall be retained for at least one year after the expiration or shelf life date of the batch.

Raw materials records shall be maintained for at least one year after the expiration or shelf life date of the last batch of product incorporating the raw material.

All records relating to the manufacture of a product including, but not limited to, maintenance, cleaning, and calibration of equipment, shall be maintained for at least one year after the expiration or shelf life date of the last batch of product produced.

Table 1 – Test methods for dietary ingredients

Dietary ingredient Latin binomial (standardized common name)	Plant part	Chemical identification method	Source of methods	Validation of method[1]
Actaea racemosa (Black Cohosh)	root/rhizome	TLC[2]	BHP	mutual recognition
Aesculus hippocastanum (Horse Chestnut)	fruit	TLC[2]	BHP	mutual recognition
Allium sativum (Garlic)	cloves	TLC[2]	USP	mutual recognition
Astragalus membranaceus (Astragalus Root)	root	TLC[2]	AHP	mutual recognition
Capsicum annuum (Cayenne)	fruit	TLC[2]	BHP	mutual recognition
Crataegus monogyna, Crataegus laevigata (Hawthorn)	berry/leaf/flower	TLC[2]	AHP	mutual recognition
Echinacea angustifolia, *Echinacea pallida* *Echinacea purpurea*, (Echinacea)	root/aerial parts	TLC[2]	BHP	mutual recognition
Eleutherococcus senticosus (Eleuthero)	root/rhizomes	TLC[2]	BHP	mutual recognition
Ganoderma lucidum (Reishi Mushroom)	whole	TLC[2]	AHP	mutual recognition
Ginkgo biloba (Ginkgo)	leaf	TLC[2]	USP	mutual recognition
Hydrastis Canadensis L. (Goldenseal)	root	TLC[2]	BHP	mutual recognition
Hypericum perforatum (St. John's Wort)	aerial parts	TLC[2]	AHP	mutual recognition
Matricaria recutita (Chamomile)	aerial parts	TLC[2]	USP	mutual recognition
Panax ginseng (Asian Ginseng) (Chinese Ginseng) (Korean Ginseng)	Root	TLC[2]	USP	mutual recognition
Piper methysticum (Kava)	rhizome	TLC[2]	BHP	mutual recognition
Serenoa repens (Saw Palmetto)	berry	TLC[2]	USP	mutual recognition
Salix daphnoides, Salix fragilis, Salix pentandra, Salix purpurea (Willow Bark)	Bark	TLC[2]	AHP	mutual recognition
Silybum marianum (Milk Thistle)	seed	TLC[2]	USP	mutual recognition
Schisandra chinensis (Schisandra Berry)	berry	TLC[2]	AHP	mutual recognition
Tanacetum parthenium (Feverfew)	aerial parts	TLC[2]	USP	mutual recognition
Uncaria tomentosa (Cat's Claw)	bark	TLC[2]	BHP	mutual recognition
Vaccinium macrocarpoon, Vaccinium oxycoccos (Cranberry Fruit)	fruit	HPLC[3]	USP	mutual recognition
Valeriana officinalis (valerian)	root	TLC[2]	AHP	mutual recognition
Viburnum opulus (Cramp Bark)	stem/root	TLC[2]	AHP	mutual recognition
Viburnum prunifolium (Black Haw Bark)	stem/root	TLC[2]	AHP	mutual recognition
Vitex agnus-castus (Chaste tree)	fruit	HPTLC[4]	AHP	mutual recognition
Withania somnifera (Ashwagandha Root)	root	TLC[2]	AHP	mutual recognition
Zingiber officinale (Ginger)	root/rhizome	TLC[2]	USP	mutual recognition

Table 1 – Test methods for dietary ingredients

[1] Methods Validation Levels (AOAC draft document dated 12/13/00)	
1. Collaborative Method Validation	8-10 laboratory validation study
2. Mutual Recognition Method Validation	3-4 laboratory validation study
3. Peer-Verified Method Validation	Single independent laboratory validation study in addition to in-house validation
4. In-House Method Validation	In-house validation study with but not limited to accuracy, precision, linearity, ruggedness, robustness, specificity, sensitivity, limit of detection, and limit of quantitation.
5. Emergency Method Validation	Validation study with two different positive and negative controls.
[2] TLC = thin layer chromatography	
[3] HPLC = high performance liquid chromatography	
[4] HPTLC = high performance thin layer chromatography	

– concluded –

Table 2 – Test methods for marker constituent compounds

Dietary ingredient Latin binomial (Standardized common name)	Marker constituent compound	Test method	Validation of method
Actaea racemosa (Black cohosh)	Actein, 26-deoxycimifigoside, Cimiracemoside A, 27-deoxyactein, Acetyl shengmanol xyloside, Cimicifugoside, Cimiracemoside F, Cimiracemoside C, and Cimiracemoside E.	INA, Black Cohosh Assay by ELSD	mutual recognition method
Allium sativum (Garlic)	Allicin	INA, Allicin by High-Performance Liquid Chromatography	in-house method
Astragalus membranaceus (Astragalus Root)	Calycosin, Formononetin, Ononin	AHP, Astragalus Flavonoids by HPLC	mutual recognition method
Camellia sinensis (Green tea)	Epigallocatechin, catechin, Epicatechin, Epigallocatechin gallate, Catechin Gallate, Gallocatechin gallate, Epicatechin Gallate and Gallic acid	INA, Catechins and Gallic Acid in Green Tea by HPLC	in-house method
Crataegus monogyna, Crataegus laevigata (Hawthorn Leaf and Flower)	Vitexin	AHP, Flavonoids in Hawthorn Leaf and Flower by HPLC	mutual recognition method
Echinacea angustifolia Echinacea pallida Echinacea purpurea (Echinacea)	Caftaric acid, Cichoric acid, Chlorogenic acid, Echinacoside	INA, Phenolics in Echinacea by HPLC	in-house method
Ginkgo biloba (Ginkgo)	Ginkogolide A, Ginkgolide B, Bilobalide	INA, Ginkoterpenoid Assay by HPLC	in-house method
Ginkgo biloba (Ginkgo)	Kaempferol, Quercetin, Isorhamnetin	INA, Ginkgo Flavonol Glycoside Assay by HPLC	in-house method
Hypericum perforatum (St. John's Wort)	Rutin trihydrate, Hyperoside, Hypericin, Quercitrin, Chlorogenic Acid, Hyperforin, Isoquercitrin, Quercetin, Pseudohypericin	INA, St. John's Wort Assay by HPLC	in-house method
Piper methysticum (Kava)	Desmethoxyyangonin, Dihydromethysticin, Dihydrokavain, Methysticin, Yangonin, Kavain	INA, Kavalactone Assay by HPLC	in-house method
Salix daphnoides, Salix fragilis, Salix pentandra, Salix purpurea (Willow Bark)	Salicin, L-Picein	AHP, Willow Bark Assay by HPLC	in-house method
Schisandra chinensis (Schisandra Berry)	Schisandrin A, Schisandrin B	AHP, Schisandra berry Assay by HPLC	mutual recognition method

Table 2 – Test methods for marker constituent compounds

Dietary ingredient Latin binomial (Standardized common name)	Marker constituent compound	Test method	Validation of method
Serenoa repens (Saw palmetto)	Hexanoic, Hexanoic, Nonanoic Decanoic, Dodecanoic, Tetradecanoic, Hexadecanoic, Heptadecanoic, Octadecanoic, 9-Octadecenoic, 9,12-Octadecadienoic, 9,12,15-Octadecatrienoic acids	INA, Fatty Acid Content in Saw Palmetto by Gas Chromatography	in-house method
Serenoa repens (Saw palmetto)	Stigmasterol, campesterol, brassicasterol, and ß-sitosterol	INA, Sterols Content in Saw Palmetto by Gas Chromatography	in-house method
Valeriana officinalis (Valerian)	Valerenic acid, acetoxyvalerenic acid, hydroxyvalerenic acid	AHP, Valerenic Acids in Valerian by HPLC	mutual recognition method
Vitex agnus-castus (Chaste tree)	Casicin	AHP, Casticin Assay in Chaste Tree Fruits by HPLC	mutual recognition method

– concluded –

Table 3 – Acceptable limits for microbiological contaminants in botanical raw materials

Ingredient	Aerobic	Yeast / Mold	Entero-bacteriaceae	*Salmonella sp.*	*E. coli*	*S. aureus*
Allium cepa (Onion)	1×10^5	1×10^4	1×10^3	absent	absent	N/A
Allium sativum (Garlic)	1×10^5	1×10^4	1×10^3	absent	absent	N/A
Aloe vera	1×10^7	1×10^5	1×10^3	absent	1×10^2	N/A
Aloe vera gel	1×10^5	1×10^4	N/A	absent	N/A	absent
Astragalus membranaceus *Astragalus mongholicus* (Astragulus)	1×10^7	1×10^5	1×10^3	absent	1×10^2	N/A
Brucea javanica (Java brucea)	1×10^7	1×10^5	1×10^3	absent	1×10^2	N/A
Bupleurum chinense (Bupleurum)	1×10^7	1×10^5	N/A	absent	1×10^2	N/A
Centella asiatica (Asiatic pennywort)	1×10^7	1×10^5	1×10^3	absent	1×10^2	N/A
Matricaria recutita (Chamomile)	1×10^7	1×10^5	1×10^3	absent	1×10^2	N/A
Cinnamomum verum (Cinnamon)	1×10^7	1×10^5	1×10^3	absent	1×10^2	N/A
Coptis chinensis (Chinese Goldthread)	1×10^7	1×10^5	1×10^3	absent	1×10^2	N/A
Curcuma longa (Common Turmeric)	1×10^7	1×10^5	1×10^3	absent	1×10^2	N/A
Echinacea angustifolia, Echinacea pallida, Echinacea purpurea, (Echinacea)	1×10^7	1×10^5	1×10^3	absent	1×10^2	N/A
Ginkgo biloba (Ginkgo)	1×10^7	1×10^5	1×10^3	absent	1×10^2	absent
Glycrrhiza echinata (Licorice)	1×10^7	1×10^5	1×10^3	absent	1×10^2	absent
Hypericum perforatum (St. John's Wort)	1×10^5	1×10^4	N/A	absent	absent	absent
Paeonia lactiflora (Chinese Peony)	1×10^7	1×10^5	1×10^3	absent	1×10^2	N/A
Panax ginseng (Asian ginseng)	1×10^7	1×10^5	1×10^3	absent	1×10^2	absent
Plantago ovata (Indian plantain)	1×10^5	1×10^4	1×10^3	absent	absent	N/A
Platycodon grandiflorum (Platycodon)	1×10^7	1×10^5	1×10^3	absent	1×10^2	N/A
Rauvolfia serpentina (Rauwolfia)	1×10^7	1×10^5	1×10^3	absent	1×10^2	N/A
Rheum palmatum (Chinese rhubarb)	1×10^7	1×10^5	1×10^3	absent	1×10^2	N/A
Senna alexandrina (Senna)	1×10^7	1×10^5	1×10^3	absent	1×10^2	N/A
Serenoa repens extract (Saw Palmetto)	1×10^5	1×10^4	N/A	absent	absent	absent
Silybum marianum extract (Milk Thistle)	1×10^5	1×10^4	N/A	absent	absent	absent
Tanacetum parthenium extract (Feverfew)	1×10^5	1×10^4	N/A	absent	absent	absent
Thymus vulgaris (Thyme)	1×10^5	1×10^4	1×10^3	absent	absent	N/A
Valeriana officinalis (Valerian)	1×10^7	1×10^5	1×10^3	absent	1×10^2	N/A
Powdered valerian extract	1×10^5	1×10^4	1×10^3	absent	absent	absent
Zingiber officinale (Ginger)	1×10^7	1×10^5	1×10^3	absent	1×10^2	absent

Units are presented in CFU/g or mL.

N/A = not applicable

Table 4 – Acceptable limits for microbiological contaminants in finished product

Finished Product	Aerobic	Yeast/ mold	Entero-bacteriaceae	*Salmonella sp.*	*E. coli*	*S. aureus*
finished products containing only vitamins and minerals	3×10^3	3×10^2	1×10^2	absent	absent	absent
other finished products	1×10^5	1×10^4	1×10^2	absent	absent	absent
Units are presented in CFU/g or mL.						

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Annex A
(normative)

Botanicals known or suspected to contain aristolochic acid[21]

Aristolochia spp.
Aristolochia acuminata
Aristolochia argentina
Aristolochia baetica
Aristolochia bracteata
Aristolochia chilensis
Aristolochia cinnabarina
Aristolochia clematitis
Aristolochia contorta
Aristolochia cymbifera
Aristolochia debilis
Aristolochia elegans
Aristolochia esperanzae
Aristolochia fangchi
Aristolochia fimbriata
Aristolochia indica
Aristolochia kaempferi
Aristolochia kwangsiensis
Aristolochia macrophylla
Aristolochia manschuriensis
Aristolochia maurorum
Aristolochia maxima
Aristolochia mollissima
Aristolochia pistolochia
Aristolochia rigida
Aristolochia rotunda
Aristolochia serpentaria
Aristolochia watsoni
Aristolochia watsonii
Aristolochia westlandi
Aristolochia westlandii
Aristolochia zollingeriana
Asarum canadense
Asarum himalacium
Asarum himalaycum
Asarum splendens
Asaum forbesii
Asarum heterotrpoides
Asarum sieboldii
Akebia spp.
Akebia quinata
Akebia trifoliate
Bragantia wallichii
Clematis spp.
Clematis armandii
Clematis chinensis
Clematis hexapetala
Clematis montana
Clematis uncinata
Cocculus spp.
Cocculus carolinus
Cocculus diversifolius
Cocculus hirsutus
Cocculus indicus
Cocculus laurifolius
Cocculus leaebe
Cocculus madagascariensis
Cocculus orbiculatus
Cocculus palmatus
Cocculus pendulus
Cocculus thunbergii
Diploclisia affinis
Diploclisia chinensis
Menispernum dauricum
Saussurea lappa
Sinomenium acutum
Stephania spp.
Stephania tetrandra
Vladimiria souliei

[21] The source of this table is an April 19, 2001 U.S. FDA correspondence from the Office of Nutritional Products, Labeling and Dietary Supplements (www.cfsan.fda.gov/~/~dms/ds-bot14.html).

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Annex B
(informative)

Reference information for contaminant level acceptance criteria

This annex contains reference information regarding the sources of information used to establish acceptance criteria for contaminant levels.

B.1 Metals

Acceptance limits for cadmium and lead were obtained from the Joint FAO/WHO Expert Committee on Food Additives, World Health Organization,[22] International Programme on Chemical Safety, Safety Evaluation of Certain Food Additives and Contaminants.

The acceptance limit for chromium was obtained from the U.S. Environmental Protection Agency[23] (1998), Integrated Risk Information System (IRIS): Hexavalent Chromium.

The acceptance limit for mercury was obtained from the U.S. Environmental Protection Agency[19] (1989), Integrated Risk Information System (IRIS): Mercury (inorganic).

The acceptance limit for arsenic was obtained from the British Herbal Pharmacopoeia.[24]

[22] World Health Organization, 1211 Geneva 27, Switzerland

[23] U.S. Environmental Protection Agency, Environmental Criteria and Assessment Office, Cincinnati, Ohio

[24] British Herbal Medicine Association, British Herbal Pharmacopoeia, 1996

B.2 Microbiological contaminants

B.2.1 The acceptance limits contained in table 3 for the following microbiological contaminants were obtained from the World Health Organization.

Allium cepa (Onion)
Allium sativum (Garlic)
Aloe vera, Aloe Vera gel
Astragalus membranaceus, *Astragalus mongholicus* (Astragulus)
Brucea javanica (Java brucea)
Bupleurum chinense (Bupleurum)
Centella asiatica (Asiatic pennywort)
Matricaria recutita (Chamomile)
Cinnamomum verum (Cinnamon)
Coptis chinensis (Chinese Goldthread)
Curcuma longa (Common Turmeric)
Echinacea angustifolia, Echinacea pallida, Echinacea purpurea; (Echinacea)
Gingko biloba (Ginkgo); *Glcyrrhiza echinata* (Licorice)
Paeonia lactiflora (Chinese Peony)
Panax ginseng (Asian ginseng,Chinese ginseng, Korena ginseng)
Plantago ovata (Psyllium seed)
Platycodon grandiflorum (Balloon flower)
Rauvolfia serpentina (Rauwolfia)
Rheum palmatum (Chinese rhubarb)
Senna alexandrina (Senna)
Thymus vulgaris (Thyme)
Valeriana officinalis (Valerian)
Zingiber officinale (Ginger)

B.2.2 The acceptance limits contained in table 3 for the following microbiological contaminants were obtained from the U.S. Pharmacopeia National Formulary.

Gingko biloba (Ginkgo)
Glcyrrhiza echinata (Licorice)*;*
Hypericum perforatum (St. John's Wort)
Panax ginseng (Asian ginseng, Chinese ginseng, Korena ginseng)
Serenoa repens (Saw Palmetto)
Silybum marianum (Milk Thistle)
Tanacetum parthenium (Feverfew)
Powdered valerian extract; *Zingiber officinale* (Ginger)

Annex C
(informative)

Calculating acceptance criteria

This annex contains information for calculating acceptance criteria for metal contamination levels for finished products.

C.1 Normalization of laboratory data

Normalization is the mathematical adjustment of laboratory results to estimate actual human exposure levels based upon the manufacturer's recommended daily dosage.

C.2 Sampling and reporting of laboratory data

The laboratory will test a quantity of sample sufficient to minimize sampling error and to reach the desired limit of detection that is required for each metal contaminant.

The laboratory results will be reported in milligrams of contaminant per gram of tested product (mg/g) for solid materials. If the product is a liquid, it will be reported as milligram contaminant per milliliter of tested product (mg/mL).

C.3 Normalization calculations

– Normalized concentration = mg contaminant / g finished product x Maximum Daily Dosage (MDD); and

– MDD = maximum dose recommended by the manufacturer on the label.

The normalized concentration is compared to the acceptance criteria for finished product.

Example:

– MDD = (2) 500mg tablets taken 3 times a day = 3g of product;

– per laboratory results, the mg contaminant/g finished product = 0.002mg lead/g finished product;

– normalized concentration = 0.006mg/d = 0.002mg lead/g finished product x 3g (MDD); and

– acceptance criteria for lead is 0.02mg/d, therefore product is acceptable.

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Standards and Criteria[25]

The following standards and criteria established and adopted by NSF as minimum voluntary consensus standards are used internationally:

2 Food equipment
3 Commercial warewashing equipment
4 Commercial cooking, rethermalization, and powered hot food holding and transport equipment
5 Water heaters, hot water supply boilers, and heat recovery equipment
6 Dispensing freezers
7 Commercial refrigerators and freezers
8 Commercial powered food preparation equipment
12 Automatic ice making equipment
13 Refuse processors and processing systems
14 Plastics piping system components and related materials
18 Manual food and beverage dispensing equipment
20 Commercial bulk milk dispensing equipment
21 Thermoplastic refuse containers
24 Plumbing system components for manufactured homes and recreational vehicles
25 Vending machines for food and beverages
29 Detergent and chemical feeders for commercial spray-type dishwashing machines
35 High pressure decorative laminates (HPDL) for surfacing food service equipment
36 Dinnerware
37 Air curtains for entranceways in food and food service establishments
40 Residential wastewater treatment systems
41 Non-liquid saturated treatment systems
42 Drinking water treatment units – Aesthetic effects
44 Residential cation exchange water softeners
46 Evaluation of components and devices used in wastewater treatment systems
49 Class II (laminar flow) biosafety cabinetry
50 Circulation system components and related materials for swimming pools, spas/hot tubs
51 Food equipment materials
52 Supplemental flooring
53 Drinking water treatment units – Health effects
55 Ultraviolet microbiological water treatment systems
58 Reverse osmosis drinking water treatment systems
59 Mobile food carts
60 Drinking water treatment chemicals – Health effects
61 Drinking water system components – Health effects
62 Drinking water distillation systems
75 Non-potentially hazardous foods
170 Glossary of food equipment terminology
173 Dietary supplements
177 Shower filtration systems – Aesthetic effects
184 Residential dishwashers
14159-1 Hygiene requirements for the design of meat and poultry processing equipment
14159-2 Hygiene requirements for the design of hand held tools used in meat and poultry processing
14159-3 Hygiene requirements for the design of mechanical belt conveyors used in meat and poultry processing

[25] The information contained in this Standards and Criteria page is not part of this American National Standard (ANS) and has not been processed in accordance with ANSI's requirements for an ANS. As such, this Standards and Criteria page may contain material that has not been subjected to public review or a consensus process. In addition, it does not contain requirements necessary for conformance to the Standard.

***THE HOPE OF MANKIND** rests in the ability of man to define and seek out the environment which will permit him to live with fellow creatures of the earth, in health, in peace, and in mutual respect.*

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